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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,352	03/17/2000	Edward L. LeCluyse	421/17/2	3016

25297 7590 01/27/2003

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/527,352**

Applicant(s)  
**LeCruise et al.**

Examiner  
**Vera Afremova**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 31, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 67-200 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 67-200 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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## DETAILED ACTION

### *Continued Prosecution Application*

The request filed on 10/31/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/527,352 is acceptable and a CPA has been established. An action on the CPA follows.

### *Status of claims*

Claims 1-11, 13-23 and 39-66 were canceled by applicants in the Paper No. 13 filed 5/31/2002. Claims 25-38 were canceled by applicants in the Paper No. 18 filed 10/31/2002.

**New claims 67-200 are pending and subject to restriction requirement [Paper No. 18 filed 10/31/2002].**

### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 67-90, drawn to a method for an *in vitro* screening a xenobiotic for susceptibility to biliary excretion in hepatocyte culture with bile canaliculus, classified in class 435, subclass 4+, for example.
- II. Claims 91-104, drawn to a method for an *in vitro* screening a xenobiotic for susceptibility to *in vivo* biliary excretion by endogenous sinusoidal and/or canalicular transport system, classified in class 435, subclass 4+, for example.

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- III. Claims 105-118, drawn to a method for an *in vitro* screening a xenobiotic for susceptibility to biliary excretion in hepatocyte cultures with intact and disrupted bile canaliculus, classified in class 435, subclass 4+, for example.
- IV. Claims 119-133, drawn to a method for an *in vitro* screening a metabolite xenobiotic and a parent xenobiotic for susceptibility to biliary excretion in hepatocyte cultures with intact and disrupted bile canaliculus, classified in class 435, subclass 4+, for example.
- V. Claims 134-157, drawn to a method for an *in vitro* screening an endobiotic for susceptibility to biliary excretion in hepatocyte culture with bile canaliculus, classified in class 435, subclass 4+, for example.
- VI. Claims 158-171, drawn to a method for an *in vitro* screening an endobiotic for susceptibility to *in vivo* biliary excretion by endogenous sinusoidal and/or canalicular transport system, classified in class 435, subclass 4+, for example.
- VII. Claims 172-185, drawn to a method for an *in vitro* screening an endobiotic for susceptibility to biliary excretion in hepatocyte cultures with intact and disrupted bile canaliculus, classified in class 435, subclass 4+, for example.
- VIII. Claims 186-200, drawn to a method for an *in vitro* screening a metabolite endobiotic and a parent endobiotic for susceptibility to biliary excretion in hepatocyte cultures with intact and disrupted bile canaliculus, classified in class 435, subclass 4+, for example.

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The inventions are distinct, each from the other because of the following reasons:

The inventions listed above are distinct methods for screening because they comprises different active steps in the methods for screening as claimed, they require applications of different culture systems of hepatocyte as claimed and they requires monitoring and/or measuring different compounds and parameters as claimed. Therefore, the methods for screening are distinct as claimed.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the Invention of Group I would not necessarily anticipate or make obvious the any of the other groups.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR1.48(b) and by the fee required under 37 CFR1.17(h).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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January 24, 2003.

VERA AFREMOVA

PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.